RESPONSES TO APPENDIX M-I-C-1
HUMAN GENE TRANSFER PROTOCOLS

RECOMBINANT DNA ADVISORY COMMITTEE MEETING
September 2001

ID #	Letter	Protocol #	Response
		0001-372	**A Phase 1, Single-Dose, Dose-Escalation Study of MiniAdFVIII Vector in Patients with Severe Hemophilia A. Sponsor: GenStar Therapeutics Corporation**
150	06/06/2001		*Response to M-I-C-1:* In response to the RAC's recommendations following the September 2000 review, a summary of the non-human primate biodistribution and transgene expression were provided. The material under Appendix M-I-C-1 of the NIH Guidelines (Jan. 2001) will be provided within 20 working days of subject enrollment.
		0005-396	**A Phase I, Open-Label, Dose-Escalating Study of the Safety, Tolerability, and Anti-Tumor Activity of a Single Intrahepatic Injection of a Genetically Modified Herpes Simplex Virus NV1020, in Subjects with Adenocarcinoma of the Colon with Metastasis to the Liver and the associated, long-term follow-up protocol: Long-Term Follow-Up of the Safety and Survival of subjects with Adenocarcinoma of the Colon with Metastasis to the Liver Who Enrolled in a Phase I Dose-Escalating Study Evaluating a Genetically Engineered Herpes Simplex Virus, NV 1020. Sponsor: NeuroVir Therapeutics, Inc.**
170	06/01/2001		*Response to M-I-C-1:* Received a copy of the IRB and IBC-approved and FDA-authorized clinical protocol for the long-term follow-up phase of this study. This portion of the study does not involve active administration of study agent. First individual was enrolled in this portion of the study on
		0105-472	**Phase I/II Study of Vaccination with Irradiated Autologous Lung Tumor Cells Mixed with a GM-CSF Secreting Bystander Cell Line (Lung Bystander GVAXR) in Advanced Non-Small Cell Lung Cancer. Sponsor: Cell Genesys, Inc.**
206	07/09/2001		*Response to M-I-C-1:* Received information in accordance with Appendix M-I-C-1 of the January 2001 NIH Guidelines. First individual was enrolled on this trial on June 28, 2001.